IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

JEFF BOGGS, on behalf of himself and all others similarly situated,	)	
Plaintiff,	)	CASE NO.
vs.	)	CLASS ACTION
DAVOL, INC., and C.R. BARD, INC.	)	**CLASS ACTION COMPLAINT AND JURY DEMAND**
Defendants.	)	

Plaintiff, Jeff Boggs, by and through his attorneys, brings this action individually and on behalf of all others similarly situated, and for his Class Action Complaint (hereinafter "Complaint"), alleges the following upon information and belief:

NATURE OF THE ACTION

1. Plaintiff brings this action on behalf of himself and the Class defined herein against C.R. Bard, Inc. ("Bard") and its wholly owned subsidiary, Davol, Inc., ("Davol"), for their sale and distribution of defective Composix Kugel Mesh Patches. The Defendants' defective product has been surgically implanted into the body of the Plaintiff and the class members. The patch presents, and will continue to present, a substantial risk of injury or death to the Plaintiff and the Class Members. As a result, Plaintiff and the class have been injured and will need continual and ongoing medical monitoring.

PARTIES

2. Plaintiff Jeff Boggs ("Mr. Boggs") is an individual citizen and resident of the State of Illinois, Wabash County. During the relevant time period, Mr. Boggs had hernia repair

surgery which included the implantation of a Composix Kugel Mesh Patch into his body. That patch remains in his body to date.

3. Defendant Davol, Inc., (hereinafter "Davol") is and was a wholly owned subsidiary of Bard, with its principal place of business at 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02920. At all times relevant, Davol was a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business for manufacturing hernia surgical repair products in Cranston, Rhode Island. Davol designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Illinois.

4. Defendant Bard is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, and at all times relevant designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Illinois. Additionally, Bard manufactures and supplies Davol with material that forms part of the Composix Kugel Mesh Patch.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over the Class pursuant to 28 U.S.C. §§ 1332(d)(2) and (6) of the Class Action Fairness Act of 2005. Plaintiff and each member of the putative Class have suffered aggregate damages exceeding five million dollars ($5,000,000),

exclusive of interest and costs. There are members of the Class who are citizens of a different State than Defendants.

6. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a) because Plaintiff resides in this judicial district and both Defendants earn substantial compensation and profits from its sales of the product in question in this district.

GENERAL ALLEGATIONS

7. This class action involves the Composix Kugel Mesh Patch manufactured by Defendants between 2001 and January 2007. These Composix Kugel Mesh Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.

8. A hernia occurs when the stomach muscles are too weak to contain the intestines, and as a result, a rupture occurs in the muscle wall which allows the intestines to protrude. The Composix Kugel Mesh Patch was designed to treat ventral hernias caused by the thinning or stretching of scar tissue that forms after surgery.

9. The Kugel Mesh line of products was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, Bard acquired the Kugel line of hernia repair products from Surgical Sense, Inc. Shortly thereafter, in 2001, Bard introduced the Composix Kugel Mesh Patch through its subsidiary, Davol.

10. The Composix Kugel Mesh Patch, invented by Dr. Robert D. Kugel, is a polypropylene mesh prosthetic device developed to repair ventral hernias, or hernias of the abdominal region. The Composix Kugel Mesh Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.

11. Due to defects in the design and manufacturing of the Composix Kugel Mesh Patch, the "memory recoil ring" that opens the patch can fail under the stress of placement of the product in the intra-abdominal space. Once the memory recoil ring has failed, it can later come loose and cause serious injuries as it travels through the body. These injuries include: intestinal perforations; ring migration through the abdominal wall; abscesses; bowel obstruction and sepsis; and chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

12. Defendants submitted their 510K Application to the Federal Drug Administration (the "FDA") on January 22, 2001. Following the 510K Application the Composix Kugel Mesh Patch was authorized by the FDA as a Class II medical device.

13. Immediately after the Composix Kugel Mesh Patches were placed on the market, Defendants began receiving actual notices of memory ring failures and Composix Kugel Mesh Patch defects. Defendants actively and intentionally concealed this notice of the defective and dangerous condition associated with the Composix Kugel Mesh Patches from Plaintiff, Plaintiff's physicians, members of the Class and the general public.

14. After the defective and dangerous patch was already placed on the market, Defendants conducted physician screenings and reviews as early as 2002. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time. Whether intentionally or negligently, Defendants failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results. These complaints and concerns of the physician surveyors were actively concealed by Defendants from Plaintiff,

Plaintiff's surgeons, members of the Class and the public at large.

15. Additionally, no later than September 2004, Defendants uncovered serious problems with the weld process involving the memory recoil ring. Despite attempts to correct the problem at the plant, Defendants found the corrective measures to be ineffective and the process still not in control. Defendants were ware these weld issues had existed from the time the Kugel Patches were originally placed on the market and all current lots suffered from this dangerous defect. This information was intentionally withheld at this time from Plaintiff, Plaintiff's physicians, members of the Class, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches using the memory recoil ring.

16. During the 2006 EIR, corporate executives informed the FDA that the spring and summer period of 2005 showed a marketed increase in the number of complaints with the Composix Kugel Mesh Patch and the memory recoil ring. In spite of their knowledge of increasing complaints and complications, Defendants waited until August 30, 2005 to initiate a partial Composix Kugel Mesh Patch distribution hold. Defendants actively and intentionally chose not to immediately inform Plaintiff, Plaintiff's physicians, members of the Class, the FDA, and all other individuals who had been implanted or would be implanted with Composix Kugel Mesh Patches using the memory recoil ring. Defendants waited until December 2005 to notify the public of the potential severity of the complications which were resulting from the dangerous and defective Composix Kugel Mesh Patches and have since admitted that the product quality hold and release procedure was not applied on a timely basis.

17. The FDA conducted the aforementioned EIR investigations in January and February of 2006. The results of these investigations determined, among other things, that

Defendants:

a. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;

b. misidentified numerous Composix Kugel Mesh Patch complication events;

c. failed to apply the product quality hold and release procedure on a timely basis;

d. failed to properly follow the procedures for conducting design validation review;

e. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Composix Kugel Mesh Patch complications; specifically, they provided no justification for including only the Extra Large Composix Kugel Mesh Patch sizes in the December 2005 recall;

f. failed to provide full information which they knew regarding numerous Composix Kugel Mesh Patch complaints;

g. failed to actually perform strength testing on memory recoil rings for all sizes of Composix Kugel Mesh Patch before putting them into the stream of commerce; and

h. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Composix Kugel Mesh Patch complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases.

18. The Composix Kugel Mesh Patches present and constitute an unreasonable risk of danger and injury in the following respects:

a. the memory recoil ring of the Composix Kugel Mesh Patch is likely to malfunction during, or after, it is implanted;

b. the Composix Kugel Mesh Patch was not properly manufactured;

c. the Composix Kugel Mesh Patch was defectively designed;

d. the Composix Kugel Mesh Patch did not perform as safely as an ordinary consumer/patient would expect;

e. the Composix Kugel Mesh Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and

f. such further and additional defects as discovery and the evidence reveal.

19. As a result of this dangerous and defective condition, and the numerous serious injuries that have resulted, the FDA issued Class 1 recalls of the X-Large Oval, Large Oval and Large Circle varieties of the Composix Kugel Mesh Patch. A Class 1 recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.

20. On December 22, 2005 and January 13, 2006, Davol and Bard announced the recall of the Composix Kugel Mesh X-Large patch. Subsequently, in March of 2006, the Defendants announced the recall of the Composix Kugel Mesh Large Patch as well.

21. Under these FDA recalls, the following products were subject to recall:

PC#0010206	Bard Composix Kugel	Extra Large Oval	8.7" x 10.7"
PC#0010207	Bard Composix Kugel	Extra Large Oval	10.8" x 13.7"
PC#0010208	Bard Composix Kugel	Extra Large Oval	7.7" x 9.7"
PC#0010209	Bard Composix Kugel	Large Oval	6.3" x 12.3"

PC#0010202	Bard Composix Kugel	Large Oval	5.4" x 7"
PC#0010204	Bard Composix Kugel	Large Circle	4.5"

22. Then, on January 10, 2007, Davol and Bard expanded the recall to include all Composix Kugel Mesh Large Oval and Large Circle Mesh patches, as well as all products manufactured from January 2004 to January 2006, that had the same component design as the recalled manufacturing lots.

23. On information and belief, as of January 2007, roughly 100,000 Composix Kugel Mesh Patches had been sold. Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States.

24. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Composix Kugel Mesh Patch in their ordinary course of business. Defendants designed, manufactured, assembled and sold the devices to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiffs and all other members of the Class.

25. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

26. Defendants' Composix Kugel Mesh Patches are uniformly defective because they possess the same potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.

27. Defendants did not timely apprise the Plaintiff, members of the Class, physicians and general public of the defect in their Composix Kugel Mesh Patches, despite Defendants' knowledge that memory recoil rings had failed due to the described defects. Defendants' concealment of a known defect from Plaintiffs and Class members equitably tolls any applicable statutes of limitation. No member of the Class could have discovered the existence of the defect in the implanted Composix Kugel Mesh Patches until at least December 27, 2005, when Defendants first began to provide notice of the recall.

28. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of the Plaintiff and the members of the Class.

29. The purpose of Defendants' conduct, directed at patients, physicians and consumers, was to create demand for and sell the Composix Kugel Mesh Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Composix Kugel Mesh Patches.

30. As a direct and proximate cause of cumulative and indivisible nature of Defendants' conduct and the recalled Composix Kugel Mesh Patches, Plaintiff and the Class have suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiff and the Class have incurred and will continue to incur damages related to the recalled Composix Kugel Mesh Patches.

NAMED PLAINTIFF'S EXPERIENCE

31. Mr. Boggs underwent a hernia repair surgical procedure on January 10, 2005, and, during the course thereof, Mr. Boggs' physician implanted a Large Oval Composix Kugel Mesh Patch into his body.

32. The Composix Kugel Mesh Patch implanted in Mr. Boggs was designed, manufactured, sold and distributed by Defendants, and was intended to be used by surgeons for hernia repair surgeries. Defendants represented these Composix Kugel Mesh Patches to be appropriate and suitable products for such purposes.

33. The Composix Kugel Mesh Patch in Mr. Boggs' body presents a serious ongoing health risk due to its defective design and/or manufacture.

34. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Composix Kugel Mesh Patch, Mr. Boggs has sustained, and will continue to sustain, injuries and damages, including, but not limited to, medical monitoring by means of increased physician follow-ups, non-invasive medical imaging and screening (such as CT scans, sonograms, and/or ultrasounds), and potential future invasive surgical and exploratory treatments.

CLASS ACTION ALLEGATIONS

35. Plaintiff brings this class action on behalf of himself and on behalf of all others similarly situated, as members of a proposed Illinois plaintiff class (the "Class") defined as follows:

> All citizens, residents or domiciliaries of the State of Illinois have had a recalled Composix Kugel Mesh Patch implanted into their person, which has not been explanted, and who have not previously filed a claim or lawsuit for personal injury, but will require medical monitoring.

This action is brought and may properly be maintained as a class action pursuant to the provisions of Rule 23(a)(1)-(4), 23(b)(2), and 23(b)(3). This action satisfies the numerosity, commonality, typicality, adequacy, predominance and superiority requirements of Rule 23.

36. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint. Specifically excluded from the proposed Class are Defendants, their officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or their officers and/or directors, or any of them; the Judge assigned to this action, and any member of the Judge's immediate family.

37. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members are unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Defendants. On information and belief, Defendants have sold roughly 100,000 defective units, and, as such, the Class includes tens of thousands of class members.

38. Common questions of fact and law exist as to all members of the Class which predominate over any questions affecting only individual members of the Class. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

a. whether there are design and/or manufacturing defects in the Composix Kugel Mesh Patch;

b. whether Defendants failed to follow U.S. Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the Composix Kugel Mesh Patch over the past several years, failed to adequately document reports of the defect, and failed to exercise adequate quality control;

c. whether Defendants' conduct in designing, manufacturing, marketing and monitoring the Composix Kugel Mesh Patch fell below the duty of care owed by Defendants to Plaintiff and Class members;

d. whether Defendants intentionally, knowingly, carelessly, recklessly, or negligently concealed information regarding the existence of a defect in the Composix Kugel Mesh Patch from the FDA, physicians, Plaintiff and the members of the Class;

e. whether Composix Kugel Mesh Patch listed in the proposed Class definition share a common and inherent design defect that causes them to break, creating a risk of injury or death to patients in whom they were implanted;

f. whether Defendants negligently, recklessly, or intentionally misrepresented the quality and usefulness of the Composix Kugel Mesh Patch;

g. whether Defendants are liable for selling a dangerously defective product;

h. whether the Class has been injured by virtue of the Defendant's deceptive business practices and conduct;

i. whether Defendants' conduct is an unconscionable practice within the meaning of the Illinois Consumer Fraud and Deceptive Business Practice Act – 815 ILCS 505 *et seq.*;

j. whether Defendants' conduct constitutes the knowing or intentional concealment, suppression, or omission of material information intended to be relied upon by others in connection with the sale of their medical devices within the meaning of the Illinois Consumer Fraud and Deceptive Business Practice Act – 815 ILCS 505 *et seq.*;

k. whether the class had been injured by virtue of Defendants' violations of the Illinois Consumer Fraud and Deceptive Business Practice Act – 815 ILCS 505 *et seq.*;

l. whether persons implanted with the Composix Kugel Mesh Patch are at increased risk of developing serious latent injury;

m. whether there exists monitoring and testing procedures which make early detection and treatment of serious injury caused by exposure to the Composix Kugel Mesh Patch possible and beneficial;

n. whether Defendants' actions support a cause of action for medical monitoring pursuant to any or all of the following statutory or common law bases:

1) the Illinois Consumer Fraud and Deceptive Business Practice Act – 815 ILCS 505 *et seq*.

2) products liability;

3) negligence; and

4) unjust enrichment.

o. whether the Class is entitled to injunctive and other equitable relief including restitution and disgorgement and, if so, the nature of such relief;

p. whether the Class is entitled to medical monitoring and treatment, at Defendants' expense; and

q. whether Defendants are liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish Defendants for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages;

39. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and the members of the Class have suffered similar injury and are facing further damages arising out of Defendants' common course of conduct, as alleged herein. The damages of each Class member were and are caused directly by Defendants' conduct, as alleged herein. Plaintiff and the members of the Class must prove the same facts in order to establish the same claims, as described herein, which apply to all Class members.

40. Plaintiff is an adequate representative of the Class because he has been implanted with a Composix Kugel Mesh Patch, has incurred medical costs relating to that device, and will continue to incur related medical expenses. Moreover, Plaintiff's interests do not conflict with

the interests of the members of the Class he seeks to represent. Plaintiff has retained experienced and competent counsel, and together Plaintiff and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of the Class members will fairly and adequately be protected by Plaintiff and his counsel.

41. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, and the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Composix Kugel Mesh Patch claims. By contrast, the Rule 23 class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

42. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Rule 23(b)(1) and/or (b)(2) because:

a. the prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Defendants;

b. the prosecution of separate actions by individual Class members would also create the risk of adjudication with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests; and

c. Defendants have acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

43. Plaintiff and the Class are consumers of the defective product and were injured by Defendants' tortuous conduct.

44. Had the Defendants not engaged in the conduct described above, Plaintiff and members of the Class would not have incurred related medical costs, would not continue to incur these costs and would not require medical monitoring of their condition.

45. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff and Class members for the Composix Kugel Mesh Patches and/or for the costs of replacing the Composix Kugel Mesh Patches that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

COUNT I
(Illinois Consumer Fraud and Deceptive Business Practice Act – 815 ILCS 505 *et seq.*)

46. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

47. Plaintiff, on behalf of himself and members of the class, brings this action pursuant to the Illinois Consumer Fraud and Deceptive Business Practice Act ("ICFDBPA") – 815 ILCS 505 *et seq.*, in that they purchased and had implanted a Composix Kugel Mesh Patch for their personal use and thereby suffered ascertainable loss as a result of Defendants' actions in violation of the Act.

48. The Composix Kugel Mesh Patches are "merchandise" at that term is defined in 815 ILCS 505 § 1(b).

49. Defendants are manufacturers, marketers and/or distributors of the Composix Kugel Mesh Patch.

50. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the Composix Kugel Mesh Patch. Additionally, Defendants falsely and deceptively misrepresented or knowingly omitted, suppressed or concealed facts of such materiality regarding the safety and efficacy of the Composix Kugel Mesh Patch to or from the FDA, that had the FDA known of such facts, the patches would have never been approved and no physician would have ever surgically implanted the patches into Plaintiff and members of the Class.

51. Defendants knew or should have known, and would have known, had appropriate testing been done, that the Composix Kugel Mesh Patch caused the aforementioned serious and potentially life threatening side effects.

52. Defendants had a clear post-manufacture duty to warn which arose when they knew, or with reasonable care should have known, that their product was defective and/or dangerous.

53. Defendants' actions constitute knowing omission, suppression or concealment of material facts, made with the intent that others will rely upon such concealment, suppression or omission, in connection with the marketing and sale of the Composix Kugel Mesh Patch.

54. Defendants' actions evidence lack of good faith, honesty in fact and observance of fair dealing so as to constitute an unconscionable commercial practice.

55. Plaintiff and the Class have been significantly exposed to a hazardous product through the tortuous conduct of Defendants. As a direct and proximate result of that exposure, Plaintiff and the Class have suffered an increased risk of incurring serious latent injury relative to individuals who do not have Defendants' mesh product surgically implanted in their bodies. This increased risk of injury makes it reasonably necessary for Plaintiff and the Class to undergo

periodic diagnostic medical examinations different from what would be prescribed in absence of the exposure to Defendants' defective device. As such, medical monitoring is necessary and reasonably certain to be incurred as a proximate result of Defendants' conduct.

56. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, severe and debilitating injuries and death. In the absence of such relief, Plaintiff and the members of the Class might not receive prompt medical care that could prolong their productive lives, increase prospects for improvement and to minimize disability.

57. There currently exists non-invasive means to detect the onset of serious injury caused by the breakage or malfunction of the Composix Kugel Mesh Patch, such that subsequent treatment would have a higher chance of success at prolonging life and reducing suffering as would exist without such monitoring and treatment.

58. The necessary monitoring regime, including the use of CT scans, is different from that normally recommended in the absence of the exposure to the Defendants' defective product, and is reasonably necessary according to contemporary scientific principals.

59. The increased susceptibility to injuries and irreparable threat to the health of Plaintiff and other Class members resulting from their exposure to these hazardous products can only be mitigated or redressed by the creation of a court-supervised medical monitoring fund to provide for a medical monitoring program, including: locating individuals with the subject patches implanted in their bodies; informing them of the potential harm from the patches; testing; preventative screening; and care and treatment of the resultant medical conditions.

60. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class are entitled to injunctive relief in the form of a court supervised medical monitoring

program, punitive damages, attorneys' fees, and costs of suit. Plaintiff and members of the Class have no adequate remedy at law in that monetary damages alone do not compensate them for the continuing nature of the harm to them, and a monitoring program which notifies them of possible injuries and aids in their treatment can prevent the greater harms which may not occur immediately, or for which there may be no noticeable symptoms, and which may be treatable if proper investigation is conducted and the health risks are diagnosed and treated before they occur or become worse.

61. As a proximate result of these violations of the Illinois Consumer Fraud and Deceptive Business Practice Act, Plaintiff and the Class have suffered ascertainable loss – economic losses that include purchase price, the cost of medical tests and services, hospital costs, and other costs incidental to the implantation and monitoring of a harmful and defective product into their bodies – for which Defendants, jointly and severally, are liable to Plaintiff and the Class for damages. The amount of these damages is to be proven at trial

62. 815 ILCS 505 § 10(a) provides Plaintiff with standing to commence this action and recover treble damages, attorney's fees and costs.

COUNT II
(Negligence)

63. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

64. At all times herein mentioned Defendants had a duty to exercise reasonable care in the course of its design, manufacture, sale, testing, marketing, advertising, promoting, distribution and warning about the Composix Kugel Mesh Patch. This duty included, among other things, to assure that the products did not cause users to suffer from unreasonable and dangerous side-effects and to warn Plaintiff and Class members of the defective nature of

Defendants' devices. Defendants breached their duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the devices, thereby causing injuries to Plaintiff and Class members.

65. At all times relevant, Defendants knew, or in the exercise of reasonable care should have known, that the Composix Kugel Mesh Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, and were unreasonably likely to injure the products' users.

66. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the aforesaid products, that they were dangerous and unsafe for the use and purpose for which they were intended.

67. Defendants knew, or should have known, that consumers such as Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care.

68. Defendants breached their duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the devices in such a manner that they were prone to fail to operate and malfunction and expose Plaintiff and Class members to injury.

69. Defendants breached their duty of reasonable care to Plaintiff and Class members by failing to notify Plaintiff and the Class at the earliest possible date of known design defects in the devices.

70. Defendants breached their duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

71. As a direct and proximate result of the carelessness and negligence of Defendants, as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain damages, and are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

72. As a direct and proximate result of Defendants' actions, Plaintiff and members of the Class have already suffered damages – including the purchase and implantation of defective and dangerous medical devices – and the will be required to pay sums to ascertain the existence, nature and extent of their injuries in the future.

73. Illinois Law permits the establishment of a medical monitoring trust fund.

74. For the reasons stated above, Defendants are liable, jointly and severably, to Plaintiff and every Class Member for injunctive and equitable relief including periodic medical monitoring.

COUNT III
(Products Liability – Failure to Warn)

75. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

76. Defendants are manufacturers and/or sellers of the Composix Kugel Mesh Patch.

77. The Composix Kugel Mesh Patches manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have know of the risk of injury from the product, they failed to provide adequate warnings to users or consumers of the product and continued to promote the products aggressively.

78. The Composix Kugel Mesh Patches manufactured and/or supplied by Defendants were unaccompanied by proper warnings regarding all possible adverse side-effects or results

associated with the design, manufacturing, implantation and/or use of the Composix Kugel Mesh Patch.

79. Defendants failed to warn the FDA of material facts regarding the safety and efficacy of the Composix Kugel Mesh Patch, such that this medical device would never have been approved, and no physician would have been able to use them as a hernia repair tool in the United States.

80 Defendants failed to warn consumers and physicians of material facts regarding the safety and efficacy of the Composix Kugel Mesh Patch

81. Defendants failed to perform adequate testing. Adequate testing would have shown that the Composix Kugel Mesh Patches possess design and manufacturing flaws resulting in serious potential side effects and health risks. Full and proper warnings with respect to these results should have been made.

82. As the producing cause and legal result of the defective condition of the Composix Kugel Mesh Patch as manufactured and/or supplied by Defendants, and as a direct and proximate result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:

a. Plaintiff and the Class have suffered a significantly increased risk of contracting a serious latent injury;

b. Plaintiff and the Class have sustained economic loss including purchase price, the cost of medical tests and services, hospital costs, and other costs incidental to the implantation and monitoring of a harmful and defective product into their bodies; and

c. Plaintiff and the Class require reasonable and necessary health care, attention and services to test for and monitor the onset of serious injury resulting from Defendants' product.

COUNT IV
(Products Liability – Defective Design)

83. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

84. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective in design or manufacturing in that, when they left the hands of the manufacturer and/or supplier, they were unreasonably dangerous because they were more dangerous than an ordinary consumer would expect and more dangerous other methods of hernia repair.

85. Alternatively, the Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective in design or manufacturing in that, when they left the hands of the manufacturer and/or supplier, the foreseeable risks exceeded the benefits associated with the design.

86. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective due to inadequate warning or instruction because Defendants knew or should have known that the product created a risk of harm to consumers and Defendants failed to adequately warn of those risks.

87. The Composix Kugel Mesh Patches manufactured and/or sold by Defendants were defective due to inadequate testing.

88. The Composix Kugel Mesh Patch manufactured and/or sold by Defendants were defective due to inadequate post-marketing warning or instruction because, after the

manufacturer knew or should have known that the product created a risk of harm to consumers and Defendants failed to adequately warn of those risks and continued to promote the product.

89. As the producing cause and legal result of the defective condition of the Composix Kugel Mesh Patch as manufactured and/or supplied by Defendants, and as a direct and proximate result of the negligence, carelessness, other wrongdoing and action(s) of Defendants described herein:

a. Plaintiff and the Class have suffered a significantly increased risk of contracting a serious latent injury;

b. Plaintiff and the Class have sustained economic loss including purchase price, the cost of medical tests and services, hospital costs, and other costs incidental to the implantation and monitoring of a harmful and defective product into their bodies; and

c. Plaintiff and the Class require reasonable and necessary health care, attention and services to test for and monitor the onset of serious injury resulting from Defendants' product.

COUNT V
(Unjust Enrichment)

90. Plaintiff re-alleges and incorporates by reference each and every allegation contained in this Complaint as though fully set forth herein.

91. Defendants have financially benefited and been enriched by the unlawful and inequitable conduct alleged herein. Defendants have reaped enormous benefits and profits from consumers as a result of the sale of these defective and unreasonably dangerous devises.

92. Defendants have knowledge of this benefit.

93. Defendants have voluntarily accepted and retained this benefit, to the economic detriment of Plaintiff and the Class.

94. The circumstances, described herein, are such that it would be inequitable for

Defendants to retain the ill-gotten benefit without paying the value thereof to Plaintiff and the Class.

95. Plaintiff and the Class are entitled to the amount of Defendants' ill-gotten gains, including interest, resulting from its unlawful, unjust, unfair and inequitable conduct in manufacturing, marketing, promoting and selling its Composix Kugel Mesh Patch products.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, pray for judgment against Defendants as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Rule 23, and appointing Plaintiff and his counsel to represent the Class;

2. For an Order establishing a medical monitoring program with a trust fund that is funded by Defendants, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that the Class members receive prompt and proper medical treatment;

3. For punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

4. For all applicable statutory damages under the consumer protection legislation;

5. For an award of treble damages where available;

6. For an award of attorneys' fees and costs;

7. For prejudgment interest and the costs of suit; and

8. For such other and further relief as this court may deem just and proper.

JURY DEMAND

Dated: September 10, 2007

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